

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Role of clonidine in management of pain after lumbar discectomy

Protocol summary

Study aim

Determine the effect of Clonidine on pain relief after lumbar disc surgery

Design

Clinical trial with control group, with parallel groups, Triple blind, 60 patients

Settings and conduct

Two engines will be used in place of placebo and in a clinical trial in two parallel groups. During the entire study period, patients, staff and surgeons will be unaware of the two main study arms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years Weight 60 to 80 kg Having satisfaction Adherence of clinical signs and symptoms to MRI findings The presence of a disc in a lumbar space in an MRI Exit criteria: History of lumbar surgery Drug Addiction or Alcohol Pregnancy and lactation Previous use of the same drugs Seizures and other neurological diseases Intervention over a diskette only involves the use of a discectomy or diskette over a disk space Use of other medications the day before or after surgery (unwanted) The patient's disability is due to retardation, aphasia, visual impairment, and other things that prevent the patient from communicating. The patient's over-standard need for opioid and analgesic neuropathic drugs History of obstructive peripheral vascular disease

Intervention groups

Intervention group: Clonidine capsule form will given to patients. Control group: Placebo capsule form will given to patients.

Main outcome variables

Post-operative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N11**

Registration date: **2019-10-20, 1398/07/28**

Registration timing: **prospective**

Last update: **2019-10-20, 1398/07/28**

Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-01-26, 2018/11/06

Expected recruitment end date

2640-06-27, 2019/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of clonidine in management of pain after lumbar discectomy

Public title

The effect of medication on reducing lumbar pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years Weight 60 to 80 kg Having satisfaction Adherence of clinical signs and symptoms to MRI findings The presence of a disc in a lumbar space in an MRI

Exclusion criteria:

History of lumbar surgery Drug or Alcohol Addiction Pregnancy and lactation Previous use of the same drugs Seizures and other neurological diseases Intervention over a diskette only involves the use of a discectomy or diskette over a disk space Use of other medications the day before or after surgery (unwanted) The patient's disability is due to retardation, aphasia, visual impairment, and other things that prevent the patient from communicating. The patient's over-standard need for opioid and analgesic neuropathic drugs History of obstructive peripheral vascular disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into case and control groups. Randomization will be done using the Gaussian command at www.random.org.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Two engines will be used in place of placebo and in a clinical trial in two parallel groups. During the entire study period, patients, staff and surgeons will be unaware of the two main study arms. The use of Visual Analogue Scale (VAS) will be done to measure pain in the lower limbs and wrists of patients receiving Clonidine and placebo. Clonidine used in the form of capsules and 2 hours before surgical intervention will be given to patients in the study group. Oral Gabapentin begins with a standard dose for the patient. The placebo capsule, taken in the shape and size and color and weight of the actual drug by the head nurse, is considered to be blind to 2 hours before surgery. Two arms of control and case will be mediated by an anesthetic protocol and a profile.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz university of medical sciences

Street address

Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street.

City

Tabriz

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East Azarbaijan

Postal code

04133357310

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.TBZMED.REC.1397.481

Health conditions studied**1****Description of health condition studied**

Post-procedural Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Post-operative pain

Timepoint

Clonidine used in capsule form and 2 hours before surgical intervention in the case group will be given to patients. After surgery for the first 24 hours and at the end of 6 hours, one physician who is blind to the study will record the parametric / VAS pain rate in the sheet. The amount of Opioid ingestion in the first 24 hours after surgery will also be measured for each patient.

Method of measurement

Using VAS (virtual analogue scale) to measure pain in the lower extremities and wrists of patients receiving clonidine and placebo.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Clonidine produced by Zahravi Tabriz Company will be given orally to the patients in the form of 0.2 mg tablet twice daily.

Category

Treatment - Drugs

2

Description

Control group: Placebo produced by Zahravi Tabriz Company will be given orally to the patients in the form of 0.2 mg tablet twice daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza hospital and Shohada hospital

Full name of responsible person

Javad Aghazadeh

Street address

Golgash street, Tabriz university of medical science.

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mahni81@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Joyban

Street address

Headquarters No. 2, Third Floor of Research & Technology Dept. Gologasht Street , Tabriz University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Aghazade

Position

Neurosurgical Specialist - Neurosurgery

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is available for sharing.

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Research and Therapeutic Use

From where data/document is obtainable

Resident of neurosurgery at Imam Reza Hospital
09143141602

What processes are involved for a request to access data/document

Three months after publication of results, the writing request were submitted in the Office of the Department of neurosurgery at Imam Reza Hospital in Tabriz and will be contacted with the relevant resident.

Comments